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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PHAM, AUDREY S	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,229	REUBI, JEAN-CLAUDE	
	Examiner	Art Unit	
	Audrey S. Pham	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-9,12-14,23-25 and 27-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3, 6-9, 12-14, 23-25, 27-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Re: Reubi

Claims 1-3, 6-9, 12-14, 23-25, 27-36 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 6, 8-9, 23,34, drawn to a method of detecting and localizing CCK receptor expressing a tumour comprising administering a composition comprising a peptide formula wherein said peptide being labeled with a radioactive metal isotope, wherein said peptide labeled with a metal atom chelated by a chelating agent, classified in class 424, subclass 1.69.

NOTE: Upon election of group I above, Applicant must further elect one sequence (SEQ ID NO) from those listed in Claims 6 and 34 as each sequence represents a separate group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as being drawn to a non-elected invention.

II. Claims 1, 2, 6, 8-9, 23,34, drawn to a method of detecting and localizing CCK receptor expressing a tumour comprising administering a composition comprising a peptide formula wherein said peptide being labeled with a radioactive metal

isotope, wherein said peptide labeled with a metal atom chelated by a compound of the general formula II, classified in class 424, subclass 1.69.

NOTE: Upon election of group II above, Applicant must further elect one sequence (SEQ ID NO) from those listed in Claims 6 and 34 as each sequence represents a separate group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as being drawn to a non-elected invention.

III. Claims 1, 6, 8-9, 23, 34, drawn to a method of detecting and localizing CCK receptor expressing a tumour comprising administering a composition comprising a peptide formula wherein said peptide being labeled with a paramagnetic metal atom chelated by a chelating agent, classified in class 424, subclass 9.323.

NOTE: Upon election of group III above, Applicant must further elect one sequence (SEQ ID NO) from those listed in Claims 6 and 34 as each sequence represents a separate group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as being drawn to a non-elected invention.

IV. Claims 1, 6, 8-9, 23, 34, drawn to a method of detecting and localizing CCK receptor expressing a tumour comprising administering a composition comprising a peptide formula wherein said peptide being labeled with a paramagnetic metal atom chelated by a compound of the general formula II, classified in class 424, subclass 9.323.

NOTE: Upon election of group IV above, Applicant must further elect one sequence (SEQ ID NO) from those listed in Claims 6 and 34 as each sequence represents a separate group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as being drawn to a non-elected invention.

V. Claims 1, 6, 7, 23, 34-35, drawn to a method of detecting and localizing CCK receptor expressing a tumour comprising administering a composition comprising a peptide formula wherein said peptide being labeled with a radioactive halogen isotope, classified in class 424, subclass 1.85.

NOTE: Upon election of group V above, Applicant must further elect one sequence (SEQ ID NO) from those listed in Claims 6 and 34 as each sequence represents a separate group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as being drawn to a non-elected invention.

VI. Claims 3, 6, 24, 34, 36, drawn to a method for the therapeutic treatment of CCK-receptor expressing a carcinoma comprising a composition, a peptide formula, said peptide being labeled with an isotope, classified in class 514, subclass 12.

NOTE: Upon election of group VI above, Applicant must further elect one sequence (SEQ ID NO) from those listed in Claims 6 and 34 as each sequence represents a separate group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as being drawn to a non-elected invention.

VII. Claims 12-14, 25, 27-31, drawn to a labeled peptide and to a pharmaceutical composition for controlling CCK-receptor expressing a tumour comprising a peptide formula wherein the peptide is attached to an isotope or atom by a chelating group, classified in class 530, subclass 300.

NOTE: Upon election of group VII above, Applicant must further elect ONE sequence represented by a SEQ ID NO from those listed in Claims 13, 14, 25, 29, 30 as each sequence represents a separate group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as being drawn to a non-elected invention.

VIII. Claims 12-14, 25, 27-31, drawn to a labeled peptide and to a pharmaceutical composition for controlling CCK-receptor expressing a tumour comprising a peptide formula wherein the peptide is attached to an isotope or atom by a compound of the general formula II, classified in class 530, subclass 300.

NOTE: Upon election of group VIII above, Applicant must further elect ONE sequence represented by a SEQ ID NO from those listed in Claims 13, 14, 25, 29, 30 as each sequence represents a separate group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as being drawn to a non-elected invention.

IX. Claims 32-33, drawn to a kit for preparing a radiopharmaceutical composition comprising a derivatized peptide formula with an inert pharmaceutically acceptable carrier, classified in class 435, subclass 810.

The inventions are distinct, each from the other for the following reasons:

The inventions of groups VII-IX and the methods of groups I-VI are related as products and processes of use. The inventions can be shown to be distinct if one of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case, the labeled peptide or the pharmaceutical composition, as claimed, can be used in a materially different process such as in methods of purification, methods of developing vaccines, methods of treating cancer or methods of developing a therapeutic inhibitor. The kit, as claimed, can be used in methods of developing a prophylactic use of said kit.

The inventions of groups VII-IX encompass multiply distinct and independent products that encompass different chemical, functional as well as structural formulas. Groups VII-VIII are drawn to a pharmaceutical composition for controlling CCK-receptor and to a labeled

peptide, which is distinct from a kit for preparing a radiopharmaceutical composition, as claimed in the invention of group IX. While the products of groups VII-VIII each is drawn a pharmaceutical composition and to a labeled peptide, each product is processed differently for its particular use. Specifically, a peptide that is labeled with a well-known chelating agent is distinct from a peptide labeled with a compound that is not well-known in the art. The claimed compound has a structure that is different from the structure of a known chelating agent and has a functional group that functions differently from a known chelating agent. Because a specific use of each product requires the product to be prepared differently and separately, each peptide or composition is considered as a patentably distinct invention. Each of these groups represents separate and distinct chemical product that is made by materially different methods, and are used in materially different methods that have different modes of operation, different functions and different effects, necessitating a different search for each product. Furthermore, searching the inventions of groups VII-VIII would impose an undue search burden since a search of a labeled peptide of one group would not be used to determine the patentability of a labeled peptide of the other groups.

The inventions of groups I-VI are materially distinct methods, which differ at least in objectives, method steps and reagents. For example, the inventions of groups I-V are each drawn to a method of detecting and localizing CCK receptor expressing a tumor, with an objective different from the group VI, which drawn to a method for the therapeutic treatment of CCK-receptor expressing a carcinoma. Additionally, even though the objectives of groups I-VI may be similar, each group differs in the reagents and steps they use to detect and localize CCK receptor expressing a tumor. For example, group I uses a peptide labeled with a radioactive metal isotope and a chelating agent, group IV uses a peptide labeled with a paramagnetic metal atom and a compound of the general formula II, and group V uses a peptide labeled with a radioactive halogen atom.

These inventions are distinct for the reasons given above and they have acquired separate statuses in the art as shown by their different classifications. The search required for one group is not required for the other groups and vice versa. For these reasons, restriction for examination purposes as indicated is proper.

Species Election

The above invention groups each contain multiple generic claims that include a plurality of alternatively usable substances or members. These alternative limitations are independent or distinct inventions such that they do not share a common utility or share a substantial structural feature disclosed as being essential to that utility. Because they are not so closely related, a search and examination of the entire claim cannot be made without undue burden. The members of the alternative groupings are described in the following:

Groups I-II, VIII-IX (Claims 1, 27-31) are generic to a plurality of disclosed patentably distinct species comprising the following radioactive metal isotopes: ^{99m}Tc, ^{203}Pb, ^{67}Ga, ^{68}Ga, ^{72}As, ^{111}In, ^{113m}In, ^{97}Ru, ^{62}Cu, ^{64}Cu, ^{52}Fe, ^{52m}Mn and ^{51}Cr.

Groups III-IV, X-XI (Claims 1, 12, 27-31) are generic to a plurality of disclosed patentably distinct species comprising the following paramagnetic metal atoms: Cr, Mn, Fe, Co, Ni, Cu, Pr, Nd, Sm, Yb, Gd, Tb, Dy, Ho and Er.

Groups V-VI, XII-XIII (Claims 1, 12, 27-31) are generic to a plurality of disclosed patentably distinct species comprising the following radioactive halogen isotopes: ^{123}I, ^{124}I, ^{125}I, ^{131}I, ^{75}Br, ^{76}Br, ^{77}Br, and ^{82}Br.

Groups I-XIV (Claim 3, 12, 23, 32, 35-36) are generic to a plurality of disclosed patentably distinct species comprising the some or all of following isotopes: ^{186}Re, ^{188}Re, ^{77}As, ^{90}Y, ^{67}Cu, ^{169}Er, ^{121}Sn, ^{127}Te, ^{142}Pr, ^{143}Pr, ^{198}Au, ^{199}Au, ^{161}Tb, ^{109}Pd, ^{165}Dy, ^{149}Pm, ^{151}Pm, ^{153}Sm, ^{157}Gd, ^{159}Gd, ^{166}Ho, ^{172}Tm, ^{169}Yb, ^{175}Yb, ^{177}Lu, ^{105}Rh, ^{111}Ag, ^{125}I, ^{131}I, ^{82}Br, ^{99}mTc, ^{203}Pb, ^{67}Ga, ^{68}Ga, ^{72}As, ^{111}In, ^{113m}In, ^{97}Ru, ^{62}Cu, ^{64}Cu, ^{52}Fe, ^{52m}Mn and ^{51}Cr.

Group V-VI (Claim 7) are generic to a plurality of disclosed patentably distinct species comprising the following isotopes: ^{123}I, ^{124}I, ^{125}I, ^{131}I, ^{75}Br, ^{76}Br, ^{77}Br, and ^{82}Br.

Groups I-VI, VIII-XIII (Claims 9, 28) are generic to a plurality of disclosed patentably distinct species comprising the following chelating agents: EDTA, DTPA, CDTA, EGTA, HBED, TTHA, DOTA, HEDTA, and TETA.

Groups I-VIII (Claims 1-3, 6-9, 12-14, 23-24) are generic to a plurality of disclosed patentably distinct species comprising the following tumors or carcinomas: small cell lung carcinoma, medullary thyroid carcinoma, breast carcinoma, stromal ovarian carcinoma, and muscle carcinoma.

Upon election of any one group described above, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from applicable to the elected group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoining Claims

NOTE:

The Examiner has required restriction between product and process claims. Where Applicant elects claim(s) directed to a product and the product claim(s) is/are subsequently found allowable, the withdrawn process claim(s) that depend(s) from or otherwise include all the limitations of the allowable product claim(s) will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if an amendment is presented prior to a final rejection or allowance, whichever is earlier. Amendment submitted after final rejection is governed by 37 CFR 1.116; amendment submitted after allowance is governed by 37 CFR 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claim(s) and process claim(s) may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the withdrawn process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Audrey S. Pham whose telephone number is (571) 272-3323. The Examiner can normally be reached during the hours of 8:30 AM - 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached during business hours at the telephone number: (571) 272-0787. The fax number for the organization, where this application or proceeding is assigned, is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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9/30/05